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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,486	09/13/2005	Kazunobu Takahashi	Q83499	8574

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EXAMINER

SCHLIENTZ, NATHAN W

ART UNIT	PAPER NUMBER
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1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/507,486	Applicant(s) TAKAHASHI ET AL.	
	Examiner Nathan W. Schlientz	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 11-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 7-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-32 are pending. Claims 1-32 are subject to an Election/Restriction requirement. The invention of Claims 7-10 was elected without traverse. Claims 1-6 and 11-32 are withdrawn from consideration as being drawn to a non-elected invention. Claims 7-10 have been examined on the merits. No claim is allowed at this time.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (a), indicates that the application should relate to only one invention, or if there is more than one invention, inclusion is permitted if they are so linked to form a single inventive concept.

Annex B, Part 1 (b), indicates that "special technical features" means those technical features which as a whole define a contribution over the prior art.

Annex B, Part 1 (c), further defines independent and dependent claims. Unity of invention is concern only in relation to independent claims. Dependent claims are defined as claims which contain all the features of another claim and are in the same category as the other claim. The category of a claim refers to the classification of claims according to subject matter, e.g. product, process, use, apparatus, means, etc.

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Annex B, Part 1 (e), indicates the permission combinations of different categories of claims. Part 1 (e(I)) states that inclusion of an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product is permissible.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-6, drawn to a compound of the formula IA.

Group II, claims 7-10, drawn to a compound of the formula IB.

Group III, claims 11-14, drawn to a compound of the formula IIB.

Group IV, claims 15, 16 and 23, drawn to a liposome containing the compound of formula IA.

Group V, claims 17-22 and 24-28, drawn to a contrast medium comprising the liposome containing the compound of formula IA.

Group VI, claims 29 and 31, drawn to a liposome containing the compound of formula IB.

Group VII, claims 30 and 32, drawn to a liposome containing the compound of formula IIB.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the claimed inventions are drawn to several compound claims, liposome claims, and contrast medium claims. The inventions listed as Groups I-III lack a common special technical feature because the compounds have different structures that inherently give them different physical and chemical properties. The inventions listed as Groups IV-VII lack a common special technical feature because the liposomes and contrast medium can be formulated with materially different compounds, and do not require the use of the compounds of inventions listed as Groups I-III. Therefore, the inventions listed as Groups I-VII lack a common special technical feature, and restriction is proper.

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Telephonic Inquiry

1. During a telephone conversation with Brett Sylvester, Esq. on 12 February 2007 a provisional election was made without traverse to prosecute the invention of Group II, claims 7-10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-6, 11-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 7-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for anthracenyl, naphthalenyl, and phenyl, does not reasonably provide enablement for all aryl groups. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the nature of the invention
- 2) the state of the prior art

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- 3) the relative skill of those in the art
- 4) the predictability of the art
- 5) the breadth of the claims
- 6) the amount of direction or guidance provided
- 7) the presence or absence of working examples
- 8) the quantity of experimentation necessary

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth herein below.

The nature of the invention

The claimed invention relates to a compound of formula IB wherein the Ar¹¹ and Ar¹² each independently represent a hydrogen atom or an aryl group.

The breadth of the claims

The claims are very broad in that they are drawn to any aryl group. An aryl group is an organic group derived from an aromatic hydrocarbon by removal of one hydrogen. Therefore, any aromatic hydrocarbon, such as fullerenes, would be included in the term aryl group.

The amount of direction or guidance provided

The specification does not provide direction or guidance with respect to making the invention commensurate in scope with the term aryl group. Preferred embodiments are anthracenyl, naphthalenyl, and phenyl, but the specification states that the type of aryl group is not particularly limited (page 11, lines 14-16).

The presence or absence of working examples

The specification only provides examples where the aryl group is iodo-substituted phenyl (pages 25-27).

The quantity of experimentation necessary

In order for a person skilled in the art at the time of the invention to determine how to make compounds commensurate in scope with the instant claims, it would require undue experimentation.

Therefore, for the aforementioned reasons, the Applicant, while being enabling for anthracenyl, naphthalenyl, and pahenyl, does not reasonably provide enablement for all aryl groups.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

2. Claims 7-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the L¹¹ and L¹² groups listed on page 18, lines 11-16, does not reasonably provide enablement for all divalent bridging groups of which main chain contains 6 or more carbon atoms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Attention is again directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth herein below.

The nature of the invention

The claimed invention relates to a compound of formula IB wherein the L¹¹ and L¹² each independently represent a divalent bridging group of which main chain contains 6 or more carbon atoms.

The breadth of the claims

The claims are very broad in that they are drawn to any divalent bridging group with 6 or more carbons.

The amount of direction or guidance provided

The specification does not provide direction or guidance with respect to making the invention commensurate in scope with the term divalent bridging group of which main chain contains 6 or more carbon atoms. Preferred embodiments are listed on page 18, lines 11-16. However, the specification does not limit the divalent bridging groups of which main chain contains 6 or more carbon atoms to the aforementioned group.

The presence or absence of working examples

The specification provides examples where the divalent bridging groups of which main chain contains 6 or more carbon atoms are $-(CH_2)_nO-$ where $n=6-30$, $-(CH_2)_n-$ where $n=6-30$, $-(CH_2)_nC(O)O-$ where $n=6-30$, $-(CH_2)_nOC(O)-$ where $n=6-30$, $-(CH_2)_nSCH_2-$ where $n=5-19$, $-(CH_2)_nNHC(O)(CH_2)_2-$ where $n=3-17$, and

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$-\text{CH}_2\text{CH}=\text{CH}(\text{CH}_2)_8-$ (pages 25-27).

The quantity of experimentation necessary

In order for a person skilled in the art at the time of the invention to determine how to make compounds commensurate in scope with the instant claims, it would require undue experimentation.

Therefore, for the aforementioned reasons, the Applicant, while being enabling for the L¹¹ and L¹² groups listed on page 18, lines 11-16, does not reasonably provide enablement for all divalent bridging groups of which main chain contains 6 or more carbon atoms.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

3. Claims 7-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for ethanolamine, trimethyl substituted ethanolamine, serine, choline, glycerin, inositol, glucose, galactose, and diethylene glycol, does not reasonably provide enablement for all functional groups containing at least one heteroatom as a substituent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

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Attention is again directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth herein below.

The nature of the invention

The claimed invention relates to a compound of formula IB wherein the R¹¹ represents a hydrogen atom or an alkyl group having two or more carbon atoms and having a functional group containing at least one heteroatom as a substituent.

The breadth of the claims

The claims are very broad in that they are drawn to any functional group containing at least one heteroatom as a substituent.

The amount of direction or guidance provided

The specification does not provide direction or guidance with respect to making the invention commensurate in scope with the functional group containing at least one heteroatom as a substituent. Preferred embodiments are listed on page 21, lines 11-12. However, the specification does not limit the functional group containing at least one heteroatom as a substituent to the aforementioned group.

The presence or absence of working examples

The specification provides examples where the functional groups containing at least one heteroatom as a substituent are trimethyl substituted ethanolamine,

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ethanolamine, serine, choline, glycerin, inositol, glucose, galactose, and diethylene glycol (pages 25-27).

The quantity of experimentation necessary

In order for a person skilled in the art at the time of the invention to determine how to make compounds commensurate in scope with the instant claims, it would require undue experimentation.

Therefore, for the aforementioned reasons, the Applicant, while being enabling for trimethyl substituted ethanolamine, ethanolamine, serine, choline, glycerin, inositol, glucose, galactose, and diethylene glycol, does not reasonably provide enablement for all functional groups containing at least one heteroatom as a substituent.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Contact Information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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